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PTO/SB/08A (08-00)

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/075,924
				Filing Date	February 12, 2002
				First Named Inventor	Rebecca REDMAN
				Group Art Unit	1646
				Examiner Name	
Sheet	1	of	5	Attorney Docket Number	INBI-009/01US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
KSJ	P1	5,994,306		Chang <i>et al.</i>	<div style="border-top: 1px solid black; width: 100%; height: 100%;"></div>
K	P2	6,025,326		Steinberg <i>et al.</i>	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>1</sup>
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T	
W	D1	ABELE-HORN, M. et al., "Decrease In Nosocomial Pneumonia In Ventilated Patients By Selective Oropharyngeal Decontamination (SOD)," <i>Intensive Care Med</i> 1997;23:187-95.		
✓	D2	AERDTS, S. et al., "Prevention Of Bacterial Colonization Of The Respiratory Tract And Stomach Of Mechanically Ventilated Patients By A Novel Regimen Of Selective Decontamination In Combination With Initial Systemic Cefotaxime," <i>J Antimicrob Chemotherapy</i> 1990;26:59-76.		
✓	D3	AERDTS, S. et al., "Antibiotic Prophylaxis Of Respiratory Tract Infection In Mechanically Ventilated Patients," <i>Chest</i> 1991;100:783-91.		
✓	D4	AERDTS, S. et al., "Prophylaxis Of Infection By Selective Decontamination In Mechanically Ventilated Patients," <i>Drugs</i> 1988;35:97-9.		
✓	D5	ARMSTRONG, P. et al., "Epidemiology Of Pseudomonas Aeruginosa In An Intensive Care Unit Using Selective Decontamination Of The Digestive Tract," <i>J Hosp Infect</i> 1992;20:199-208.		
✓	D6	ARNOW, P. et al., "Randomized Controlled Trial Of Selective Bowel Decontamination For Prevention Of Infections Following Liver Transplantation" <i>Clin Infect Dis</i> 1996;22:997-1003.		
W	D7	"ASHP Therapeutic Guidelines for Nonsurgical Antimicrobial Prophylaxis. American Society of Health-System Pharmacists," <i>Am J Health Syst Pharm</i> 1999;56:1201-50.		
✓	D8	BERGMANS, D. et al., "Prevention Of Ventilator-Associated Pneumonia By Oral Decontamination," <i>Am J Resp Crit Care Med</i> Vol. 164, pp. 382-388, 2001		
W	D9	BION, J. et al., "Selective Decontamination Of The Digestive Tract Reduces Gram-Negative Pulmonary Colonization But Not Systemic Endotoxemia In Patients Undergoing Elective Liver Transplantation," <i>Crit Care Med</i> 1994;22:40-49.		
W	D10	BLAIR, P. et al., "Selective Decontamination Of The Digestive Tract: A Stratified, Randomized, Prospective Study In A Mixed Intensive Care Unit," <i>Surgery</i> 1991;110:303-309.		
✓	D11	BONTEN, M. et al., "Colonization in Patients Receiving and Not Receiving Topical Antimicrobial Prophylaxis," <i>American Journal of Respiratory and Critical Care Medicine</i> , 1994; 150:1332-1340		
✓	D12	BRUN-BUISSON, C. et al., "Intestinal Decontamination For Control Of Nosocomial Multiresistant Gram-Negative Bacilli," <i>Annals of Intern Med</i> 1989;110:873-81.		
W	D13	CERRA, F. et al., "Selective Gut Decontamination Reduces Nosocomial Infections And Length Of Stay But Not Mortality Or Organ Failure In Surgical Intensive Care Unit Patients," <i>Arch Surg</i> 1992;127:163-167.		
W	D14	COCKERILL, F. et al., "Prevention Of Infection In Critically Ill Patients By Selective Decontamination Of The Digestive Tract," <i>Annals of Intern Med</i> 1992;117:545-553.		
✓	D15	COOK, D. et al., "Rules Of Evidence And Clinical Recommendations On The Use Of Antithrombotic Agents," <i>Chest</i> 1992;102:305S-311S.		
✓	D16	D'AMICO, R. et al., "Effectiveness Of Antibiotic Prophylaxis In Critically Ill Adult Patients: Systematic Review Of Randomised Controlled Trials," <i>BMJ</i> 1998;316:1275-85.		
✓	D17	DERISO, A. et al., "Chlorhexidine Gluconate 0.12% Oral Rinse Reduces The Incidence Of Total Nosocomial Respiratory Infection And Nonprophylactic Systemic Antibiotic Use In Patients Undergoing Heart Surgery," <i>Chest</i> 1996;109:1556-1561.		
✓	D18	FERRER, M. et al., "Utility Of Selective Digestive Decontamination In Mechanically Ventilated Patients," <i>Annals of Intern Med</i> 1994;120:389-395.		

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✓	D19	FLAHERTY, J. et al., "Pilot Trial Of Selective Decontamination For Prevention Of Bacterial Infection In An Intensive Care Unit," <i>J Infect Dis</i> 1990;162:1393-1397.	
✓	D20	FLEISS, J., "The Statistical Basis Of Meta-Analysis," <i>Statistical Methods in Medical Research</i> 1993;2:121-146.	
✓	D21	GARCIA, M. et al., "Effectiveness And Cost Of Selective Decontamination Of The Digestive Tract In Critically Ill Intubated Patients," <i>Am J Respir Crit Care Med</i> 1998;158:908-916.	
✓	D22	GASTINNE, H. et al., "A Controlled Trial In Intensive Care Units Of Selective Decontamination Of The Digestive Tract With Nonabsorbable Antibiotics," <i>N Engl J Med</i> 1992;326:594-599.	
✓	D23	GEORGES, B. et al., "Décontamination Digestive Selective Resultats D'une Etude Chez Le Polytraumatise," <i>Réanimation Urgences</i> 1994;3:621-627.	
✓	D24	GODARD, J. et al., "Intestinal Decontamination In A Polyvalent ICU," <i>Intensive Care Med</i> 1990;16:307-311.	
✓	D25	HAMMOND, J. et al., "Double-Blind Study Of Selective Decontamination Of The Digestive Tract In Intensive Care," <i>Lancet</i> 1992;340:5-9.	
✓	D26	HAMMOND, J. et al., "Selective Decontamination Of The Digestive Tract In Multiple Trauma Patients—Is There A Role? Results Of A Prospective, Double-Blind, Randomized Trial," <i>Crit Care Med</i> 1994;22:33-39.	
✓	D27	HAMMOND, J. et al., "Is There A Role For Selective Decontamination Of The Digestive Tract In Primarily Infected Patients In The ICU?," <i>Anaesth Intensive Care</i> 1995;23:168-174.	
✓	D28	HAMMOND, J. et al., "Neurologic Disease Requiring Long-Term Ventilation. The Role Of Selective Decontamination Of The Digestive Tract In Preventing Nosocomial Infection," <i>Chest</i> 1993;104:547-551.	
✓	D29	HARTENAUER, U. et al., "Infection Surveillance And Selective Decontamination Of The Digestive Tract (SDD) In Critically Ill Patients—Results Of A Controlled Study," <i>Infection</i> 1990;18:S22-30.	
✓	D30	HEYLAND, D. et al., "Selective Decontamination Of The Digestive Tract," <i>Chest</i> 1994;105:1221-9.	
✓	D31	HURLEY, J., "Prophylaxis With Enteral Antibiotics In Ventilated Patients: Selective Decontamination Or Selective Cross-Infection?" <i>Antimicrob Agents Chemotherapy</i> 1995;35:941-7.	
✓	D32	JACOBS, S. et al., "Effectiveness Of Selective Decontamination Of The Digestive Tract (SDD) In An ICU With A Policy Of Encouraging A Low Gastric pH," <i>Clin Intensive Care</i> 1992;3:52-58.	
✓	D33	JADAD, A. et al., "Assessing The Quality Of Reports Of Randomized Clinical Trials: Is Blinding Necessary?" <i>Controlled Clinical Trials</i> 1996;17:1-12.	
✓	D34	KERVER, A. et al., "Prevention Of Colonization And Infection In Critically Ill Patients: A Prospective Randomized Study," <i>Crit Care Med</i> 1988;16:1087-1093.	
✓	D35	KOLLEF, M. "The Role Of Selective Digestive Tract Decontamination On Mortality And Respiratory Tract Infections," <i>Chest</i> 1994;105:1101-1108.	
✓	D36	KOLLEF, M. "The Prevention of Ventilator-Associated Pneumonia," <i>NEJM</i> 1999; 340:627-634; 341:293-294	
✓	D37	KOLLEF, M. et al., "A Randomized Clinical Trial of Continuous Aspiration of Subglottic Secretions in Cardiac Surgery Patients," <i>Chest</i> 1999;116:1339-1346	
✓	D38	KORINEK, A. et al., "Selective Decontamination Of The Digestive Tract In Neurosurgical Intensive Care Unit Patients: A Double-Blind, Randomized, Placebo-Controlled Study," <i>Crit Care Med</i> 1993;21:1466-1473.	

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
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	D39	LAGGNER, A. et al., "Oropharyngeal Decontamination With Gentamicin For Long-Term Ventilated Patients On Stress Ulcer Prophylaxis With Sucralfate?" <i>Wein Klin Wochenschr</i> 1994;106:15-19		
	D40	LANGLOIS-KARAGA, A. et al., "Selective Digestive Decontamination In Multiple Trauma Patients: Cost And Efficacy," <i>Pharm World Sci</i> 1995;17:12-6.		
	D41	LEDINGHAM, I. et al., "Triple Regimen of Selective Decontamination of the Digestive Tract, Systemic Cefotaxime, and Microbiological Surveillance for Prevention of Acquired Infection in Intensive Care," <i>Lancet</i> , April 9, 1988; 785-790		
	D42	LIBERATI, A. et al., "Antibiotics for Preventing Respiratory Tract Infections in Adults Receiving Intensive Care," (Cochrane Review), In: <i>Cochrane Library</i> , Issue 3, 2000 Oxford: Update Software		
	D43	LINGNAU, W. et al., "Changing Bacterial Ecology During A Five Year Period Of Selective Intestinal Decontamination," <i>J. Hosp Infect</i> 1998; 39:195-206		
	D44	LINGNAU, W. et al., "Selective Intestinal Decontamination In Multiple Trauma Patients: Prospective, Controlled Trial," <i>J Trauma</i> 1997;42:687-694		
	D45	LIPMAN, J. et al., "Unique Trial Design Shows SDD To Decrease And Alter Colonization Of Upper Respiratory Tract In A Multidisciplinary ICU," <i>Crit Care Med</i> 1994;144		
	D46	LUITEN, E. et al., "Controlled Clinical Trial Of Selective Decontamination For The Treatment Of Severe Acute Pancreatitis," <i>Annals of Surgery</i> 1995;222:57-65		
	D47	McCLELLAND, P. et al., "Reducing Sepsis in Severe Combined Acute Renal and Respiratory Failure by Selective Decontamination of the Digestive Tract," <i>Crit Care Med</i> , 1990;18:935-939		
	D48	"Meta-Analysis Of Randomised Controlled Trials Of Selective Decontamination Of The Digestive Tract," <i>BMJ</i> 1993;307:525-532		
	D49	MISSET, B. et al., "Short-term Impact of the European Consensus Conference on the Use of Selective Decontamination of the Digestive Tract with Antibiotics in ICU Patients," <i>Intensive Care Med</i> . 1996; 22:981-985		
	D50	MISSET, B. et al., "Bacteriological Side Effects of Gut Decontamination with Polymyxin E, Gentamicin, and Amphotericin B," <i>Infection Control and Hospital Epidemiology</i> , 1993; 14:62-64		
	D51	MISSET, B. et al., "Mechanisms of Failure to Decontaminate the Gut with Polymyxin E, Gentamicin and Amphotericin B in Patients in Intensive Care," <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , 1994; 13:165-170		
	D52	MORAR, P. et al., "Topical Antibiotics on Tracheostoma Prevents Exogenous Colonization and Infection of Lower Airways in Children," <i>Chest</i> 2000; 117:513-518		
	D53	NARDI, G. et al., "Epidemiological Impact of Prolonged Systematic Use of Topical SDD on Bacterial Colonization of the Tracheobronchial Tree and Antibiotic Resistance," <i>Internal Care Med</i> 1993;19:273-278		
	D54	NATHENS, A. et al., "Selective Decontamination Of The Digestive Tract In Surgical Patients: A Systematic Review Of The Evidence," <i>Arch Surg</i> 1999;134:170-6		
	D55	PALOMAR, M. et al., "Prevention Of Nosocomial Infection In Mechanically Ventilated Patients: Selective Digestive Decontamination Versus Sucralfate," <i>Clin Intensive Care</i> 1997;8:228-235		
	D56	PITTET, D., "Prevention of Ventilator-associated Pneumonia by Oral Decontamination," <i>Am J Resp Crit Care Med</i> , 2000; 164:338-339		
	D57	POTGIETER, P. et al., "Prophylactic Use of the New Quinolones for Prevention of Nosocomial Infection in the Intensive Care Unit," <i>Drugs</i> , 1995; 49 (Suppl.2):86-91		

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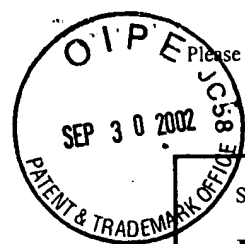
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W	D58	PUGIN, J. et al., "Oropharyngeal Decontamination Decreases Incidence Of Ventilator-Associated Pneumonia. A Randomized, Placebo-Controlled, Double-Blind Clinical Trial," <i>JAMA</i> 1991;265:2704-2710	
	D59	QUINIO, B. et al., "Selective Decontamination Of The Digestive Tract In Multiple Trauma Patients. A Prospective Double-Blind, Randomized, Placebo-Controlled Study," <i>Chest</i> 1996;109:765-72	
	D60	ROCHA, L. et al., "Prevention Of Nosocomial Infection In Critically Ill Patients By Selective Decontamination Of The Digestive Tract," <i>Intensive Care Med</i> 1992;18:398-404	
	D61	RODRIGUEZ-ROLDAN, J. et al., "Prevention Of Nosocomial Lung Infection In Ventilated Patients: Use Of An Antimicrobial Pharyngeal Nonabsorbable Paste," <i>Crit Care Med</i> 1990;18:1239-42	
	D62	ROLANDO, N. et al., "Prospective Controlled Trial Of Selective Parenteral And Enteral Antimicrobial Regimen In Fulminant Liver Failure," <i>Hepatology</i> 1993;17:196-201.	
	D63	RUZA, F. et al., "Prevention Of Nosocomial Infection In A Pediatric Intensive Care Unit (PICU) Through The Use Of Selective Digestive Decontamination," <i>Eur J. Epidemiol</i> 1998;14:719-27.	
	D64	SABAT, M. et al., "Parenteral Antibiotic Prophylaxis Of Bacterial Infections Does Not Improve Cost-Efficacy Of Oral Norfloxacin In Cirrhotic Patients With Gastrointestinal Bleeding," <i>Am J Gastroenterol</i> 1998;93:2457-h2.	
	D65	SAUNDERS, G. et al., "Microbiological Surveillance During Selective Decontamination Of The Digestive Tract (SDD)," <i>J. Antimicrobial Chemo.</i> 1994; 34:529-44.	
	D66	SCHARDEY, H. et al., "The Prevention Of Anastomotic Leakage After Total Gastrectomy With Local Decontamination. A Prospective, Randomized, Double-Blind, Placebo-Controlled Multicenter Trial," <i>Ann Surg</i> 1997;225:172-80.	
	D67	SILVESTRI, L. et al., "Selective Decontamination Of The Digestive Tract: A Life Saver," <i>J Hosp Infect</i> 2000;45:185-90.	
	D68	SMITH, S. et al., "Selective Decontamination In Pediatric Liver Transplants. A Randomized Prospective Study," <i>Transplantation</i> 1993;55:1306-9.	
	D69	STOUTENBEEK, C. et al., "Nosocomial Gram-Negative Pneumonia In Critically Ill Patients. A 3-Year Experience With A Novel Therapeutic Regimen," <i>Intensive Care Med</i> 1986;12:419-23.	
	D70	STOUTENBEEK, C. et al., "The Effect Of Selective Decontamination Of The Digestive Tract On Colonisation And Infection Rate In Multiple Trauma Patients," <i>Intensive Care Med</i> 1984;10:185-92.	
	D71	STOUTENBEEK, C. et al., "The Prevention Of Superinfection In Multiple Trauma Patients," <i>J Antimicrob Chemo.</i> (1984) 14, Suppl. B pp. 203=211	
	D72	STOUTENBEEK, C. et al., "Prevention Of Pneumonia By Selective Decontamination Of The Digestive Tract (SDD)," <i>Intensive Care Medicine</i> , 18: 518-523, 1992	
	D73	STOUTENBEEK, C. et al., "The Effect Of Oropharyngeal Decontamination Using Topical Nonabsorbable Antibiotics On The Incidence Of Nosocomial Respiratory Tract Infections In Multiple Trauma Patients," <i>J Trauma</i> , Vol 27, No. 4, pp. 357-364, 1987	
	D74	TABLAN, O. et al., "Guideline For Prevention Of Nosocomial Pneumonia," <i>Infection Control and Hospital Epidemiology</i> , Vol 15, No. 9, 587-627, September 1994	
	D75	TETTEROO, G. et al., "Selective Decontamination To Reduce Gram-Negative Colonisation And Infections After Oesophageal Resection," <i>Lancet</i> 1990;335:704-7.	
	D76	TETTEROO, G. et al., "Effects Of Selective Decontamination On Gram-Negative Colonisation, Infections And Development Of Bacterial Resistance In Esophageal Resection," <i>Intensive Care Med</i> 1990;16:S224-8.	

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✓	D77	TORRES, A. et al., "Gastric And Pharyngeal Flora In Nosocomial Pneumonia Acquired During Mechanical Ventilation," <i>Ame Rev Resp Dis</i> Vol. 148, pp. 352-357, 1993		
	D78	ULRICH, C. et al., "Selective Decontamination Of The Digestive Tract With Norfloxacin In The Prevention Of ICU-Acquired Infections: A Prospective Randomized Study," <i>Intensive Care Med</i> 1989;15:424-31.		
	D79	UNERTL, K. et al., "Prevention Of Colonization And Respiratory Infections In Long-Term Ventilated Patients By Local Antimicrobial Prophylaxis," <i>Intensive Care Med</i> 1987;13:106-13.		
	D80	VAN UFFELEN, R. et al., "Preventing Lower Airway Colonization And Infection In Mechanically Ventilated Patients," <i>Crit Care Med</i> , pp. 99-102, 1987		
	D81	VANDENBROUCKE-GRAULS, C. et al., "Effect Of Selective Decontamination Of The Digestive Tract On Respiratory Tract Infections And Mortality In The Intensive Care Unit," <i>Lancet</i> , Vol. 338, Oct. 5, 1991, pp. 859-862		
	D82	VERWAEST, C. et al., "Randomized, Controlled Trial Of Selective Digestive Decontamination In 600 Mechanically Ventilated Patients In A Multidisciplinary Intensive Care Unit," <i>Crit Care Med</i> 1997;25:63-71.		
	D83	WIENER, J. et al., "A Randomized, Double-Blind, Placebo-Controlled Trial Of Selective Digestive Decontamination In A Medical-Surgical Intensive Care Unit," <i>Clin Infect Dis</i> 1995;20:861-7.		
	D84	WINTER, R. et al., "A Controlled Trial Of Selective Decontamination Of The Digestive Tract In Intensive Care And Its Effect On Nosocomial Infection," <i>J Antimicrob Chemother</i> 1992;30:73-87.		
✓	D85	ZOBEL, G. et al., "Reduction Of Colonization And Infection Rate During Pediatric Intensive Care By Selective Decontamination Of The Digestive Tract," <i>Crit Care Med</i> 1991;19:12 12-6.		

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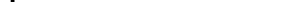
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<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	10/075,924	
		Filing Date	February 12, 2002	
		First Named Inventor	Rebecca REDMAN	
		Group Art Unit	1646	
		Examiner Name	Not yet assigned.	
Sheet		of	Attorney Docket Number	INBI-009/01US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
km	D86	VESOLE <i>et al.</i> , "IB-367 Reduces the Number of Days of Severe Oral Mucositis Complicating Myeloablative Chemotherapy," Blood – Journal of American Society of Hematology, 15 November, 1999, Abstract 675, Vol. 94, No. 10, Supplement 1, New Orleans, Louisiana.		
	D87	HANCOCK <i>et al.</i> , "Cationic Antimicrobial Peptide Antibiotics," Current Opinion in Anti-infective Investigational Drugs. 2000, Vol. 2, No. 2, pages 40-144.		
	D88	REDMAN <i>et al.</i> , "Analysis of Respiratory and Non-Respiratory Infections in Published Trials of Selective Digestive Decontamination," 2001 ESICM Meeting, European Society of Intensive Care Medicine.		
	D89	REDMAN <i>et al.</i> , "A Phase I/IIa Safety and Microbial Kinetic Study of Isegran (IB-367) Oral Solution in Intubated Patients Receiving Mechanical Ventilation," VAP study 09-001 presentation, 2001 ESICM Meeting, European Society of Intensive Care Medicine.		
	D90	REDMAN <i>et al.</i> , "A phase I Safety, Tolerability, Acceptability and Microbial Kinetic Study of Topical Isegran (previously referred to as IB-367) Gel and Rinse In Orally Intubated Patients Receiving Mechanical Ventilation," Summary of Study Results, VAP study 09-001		
	D91	REDMAN <i>et al.</i> , "Selective Decontamination of the Digestive Tract of Intensive Care Patients: A Meta-Analysis of Patient Selection and Secondary Endpoints, Meta-analysis of SDD in ICU patients," VAP Outcomes Scientific Advisory Group.		
km	D92	REDMAN <i>et al.</i> , "Phase I Safety and Microbial Kinetic Study of Oral-Topical IB-367 Rinse and Gel in Intubated Patients Receiving Mechanical Ventilation," 2001 SCCM 30 <sup>th</sup> International Educational & Scientific Symposium, Washington University School of Medicine, St. Louis, Missouri.		

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Examiner Signature		Date Considered	12/1/03
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<sup>1</sup> Unique citation designation number.

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